Washington State Department of Labor and Industries
Office of the Medical Director

Technology Assessment
Percutaneous Neuromodulation Therapy

January 13, 2004

I. Introduction

Percutaneous Neuromodulation Therapy (PNT), also known as percutaneous electrical nerve stimulation (PENS), is a procedure intended to relieve and manage chronic or intractable low back pain (LBP). (White 2001) In a manner similar to electroacupuncture, PNT uses non-implantable needles positioned in the soft tissues or muscles to stimulate peripheral sensory nerves with electricity. While electroacupuncture needles are placed at acupoints depending on patient pain, PNT generally uses a standard needle placement montage. (Hsieh 2002)

PNT may act by inhibiting C fiber afferent activity. Borg-Stein suggests that PNT may prevent early stage pain sufferers from becoming chronic patients by preventing initial peripheral pain from centralizing. (Borg-Stein 2003)

Frequency, duration, and location of the applied electrical stimulation may influence response to PNT. Studies suggest that a 15 and 30 Hz alternating frequency is more effective than low or high frequency alone. (Ghoname 1999) The optimal duration of the electrical stimulation ranges from 30 to 45 minutes. (White 2001) Needles are inserted to a depth of approximately 3 cm.

II. Food and Drug Administration Status

The Food and Drug Administration (FDA) does not regulate PNT as a therapy. However, the agency does approve for marketing the acupuncture needles and needle electrodes used in the procedures. For example, the FDA granted Vertis Neuroscience 510(k) approval for its needle electrodes in 2001. The Control Unit and Safeguide Kit are classified under "Nerve, Stimulator, Electrical, Percutaneous (PENS) for Pain Relief". (FDA 2001)

III. PNT/PENS

A. Needle Positioning

White's randomized, cross-over study suggested that a specific placement pattern resulted in the greatest benefit compared to 3 other montages. The pattern is described below. (White 2001)

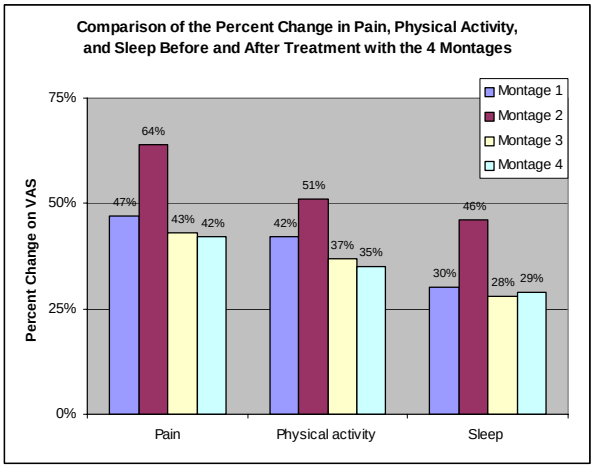
1. The top pair of electrodes spans T12 with each electrode approximately 3 cm on either side of the spinous process.
2. The mid-lumbar bilateral electrodes each have a medial electrode placed 3 cm from the spinous process at L3 and a lateral electrode placed 12 cm from the midline above the highest point of the iliac crest.
3. The most caudal bilateral electrodes each have a medial electrode at L5-S1 at a distance of 3 cm from the spinous process and lateral electrode two-thirds along the line from the posterior superior iliac spine to the greater trochanter.

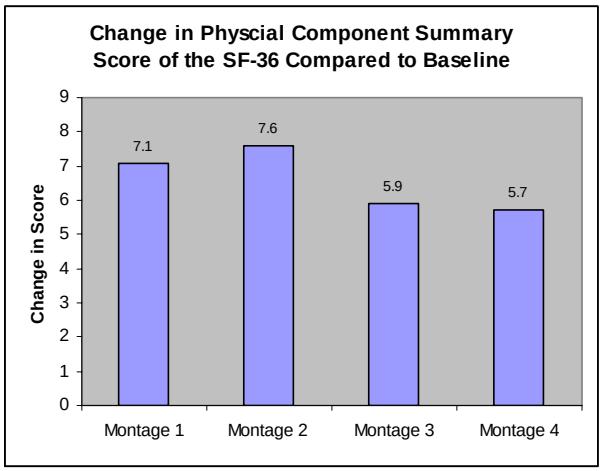
All patients received 4 different montages over the 11-week study period. They underwent treatment for 30 minutes, 3 times per week for 2 weeks with 1-week between treatments. Researchers measured LBP, physical activity, quality of sleep, daily analgesic intake, and SF-36. A pain VAS was repeated 5 to 10 minutes after each treatment to assess the acute response.

A power analysis showed that 72 subjects would demonstrate a 17% difference on the pain VAS.

Study population: The 72 patients experienced LBP for more than 6 months. Patients had radiologically confirmed degenerative lumbar spine disease with stable pain levels and analgesic use. Patients were excluded due to LBP with a radicular component, change in severity or character of pain within the last 3 months, or recent change in medication.

Results: The magnitude of change for Montages 1 and 2 were significantly greater than for Montages 3 and 4 for improving the physical and mental components of the SF-36.





B. Case Series Studies of PNT for LBP

i. Borg-Stein's case series study examined the effect of PNT on LBP. (Borg-Stein 2003) The study used a PNT control unit that delivered current to five electrode pairs. Pulse repetition frequency varied from 4 Hz to 10 Hz. Each electrode consisted of a 3-cm stainless steel filament (0.25 mm diameter) with an adhesive rim for skin contact. The current intensity was increased to the highest tolerable level without causing discomfort or muscle contractions.

All subjects underwent treatment weekly for 30 minutes. After the first four weeks, patients had the option of continuing for up to 12 weeks. Patients who benefited at the 12-week point were followed for an additional 12 weeks.

The researchers used a VAS to measure LBP, lower extremity pain, and the effect of pain on sleep and activity level. The study also measured Oswestry scores, frequency of medication, interest in pursuing surgery, and mood.

Study Population: Of the 83 patients who met criteria, 59 completed the study.

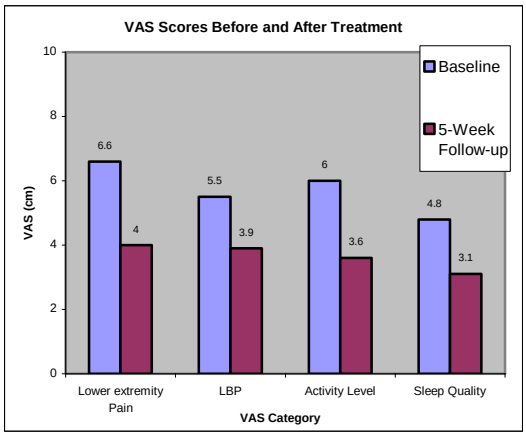
Patient Baseline Demographics

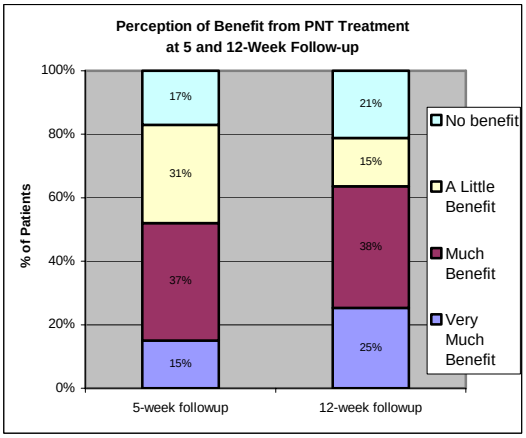
average age	53 years
average LBP VAS	5.5
average lower extremity pain VAS	6.6
most common diagnoses	
degenerative disc disease	58%
symptomatic disc protrusion/herniation	49%
myofascial pain syndrome	47%

The study included subjects with new or worsening radiating leg and/or buttock pain associated with LBP. Subjects experienced the subacute pain for between 4 weeks and 6 months. The average radiating lower extremity pain VAS score was greater than or equal to 4.

Subjects were excluded due to symptom improvement in the past 2 weeks, implanted device, systemic illness, peripheral neuropathy, unemployment, or compensable injury or workers' compensation claims.

Results: At 5-week follow-up, 37 (63%) of the 59 patients had at least a 30% decrease in their lower extremity pain score. This represents 45% of all 83 enrolled patients. Oswestry scores improved by 24% from 43 to 32.





Conclusion: For patients with subacute radiating LBP, PNT reduced pain and improved sleep quality and activity level. PNT is safe and generally well tolerated.

ii. Seroussi's case series study examined the effect of PNT on chronic and severe LBP. (Seroussi 2003) The study measured outcomes with a pain body diagram, average LBP VAS, physical activity and sleep VAS, Oswestry scores, and oral analgesic intake. The primary endpoint was the percent of subjects with at least 30% improvement on the LBP VAS or the activity VAS at final follow-up.

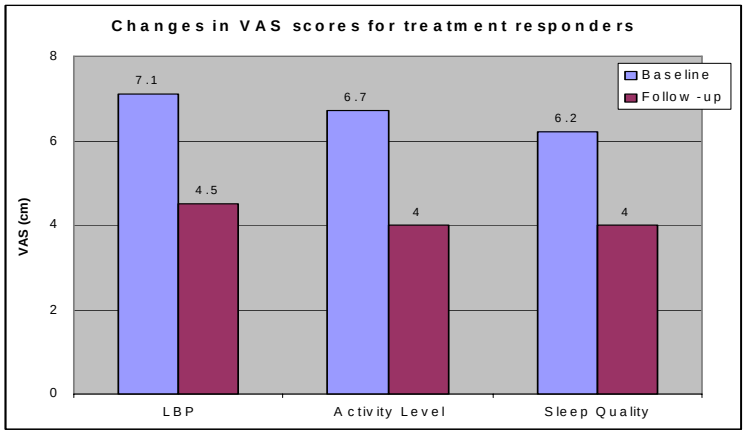
Subjects underwent treatment for 30 minutes, 2 times per week, for up to 4 weeks. Before the fifth treatment, subjects answered questions that determined response to PNT. Subjects who indicated LBP relief or increased level of activity continued with PNT.

Study Population: The study included subjects with severe axial LBP of at least 6 months duration. Subjects were excluded for the following reasons:

1. LBP intensity in the previous month was less than 5 on the VAS.
2. greater lower extremity pain compared to LBP during the preceding month.
3. significant changes in LBP severity within the previous 4 weeks.
4. unemployment, personal injury litigation, or workers' compensation claim.

While 39 patients met entry criteria, 7 electively discontinued treatment, and 1 was excluded due to leg pain. Of these 31 patients, 18 (58%) passed the responder questionnaire and completed the remaining 4 treatments. The average duration of pain was 7.7 years for responders and 10.4 years for nonresponders.

Results: Among the patients who passed the responder screen, Oswestry scores improved from 44 to 33. In addition, 14 subjects (78%) improved by at least 30% in LBP and/or activity limitation. This represents 37% of all 38 enrolled patients.



Conclusion: For patients with chronic and severe stable levels of LBP, PNT appears promising for pain level reduction and improvement in function.

C. Randomized studies

i. Ghoname's randomized, sham-controlled cross-over study evaluated the effect of different stimulation frequencies on analgesic response in patients with LBP. The study evaluated pain scores, physical activity, sleep quality, sense of well-being, SF-36, and analgesic requirement per day. (Ghoname 1999)

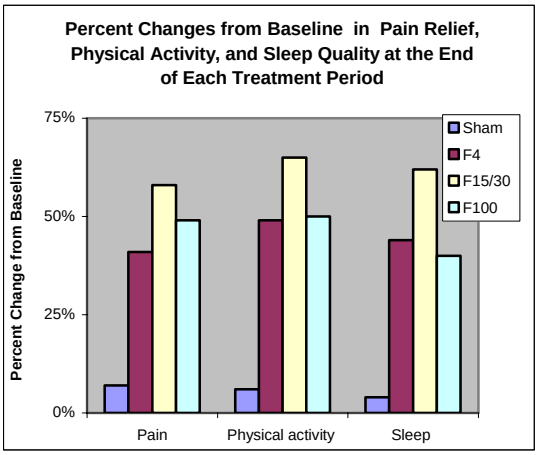
Patients received the following frequencies for 30 minutes, 3 times per week for 2 consecutive weeks with a week off between each treatment modality. The 4 options were compared 72 hours after final treatment.

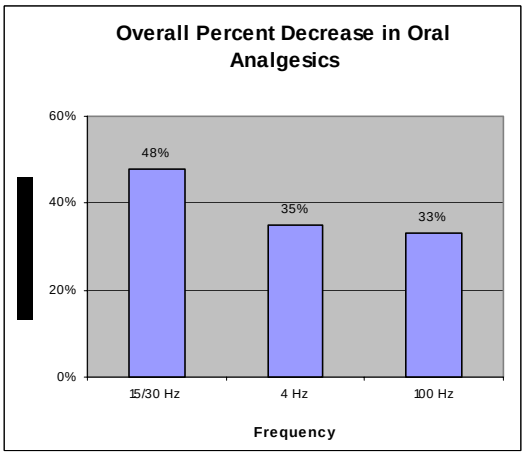
1. Sham PENS (no electrical stimulation)
2. PENS at 4 Hz
3. PENS with alternating 15 Hz and 30 Hz (15/30) switching every 3 seconds
4. PENS with 100 Hz

A power analysis indicated that 60 subjects would demonstrate a difference of 25% on pain VAS scores.

Study Population: Researchers enrolled 68 patients (mean age 46 years) with LBP associated with radiologically confirmed degenerative disc disease. Patients' LBP remained unchanged on a stable oral nonopioid analgesic for at least 3 months. Subjects were excluded due to LBP with a radicular component.

Results: While electrical stimulation showed significant improvement for both the physical and mental components of the SF-36, the sham treatment did not show any significant improvement.





Patient Preference by Frequency

Frequency	Percent of patients that preferred
15/30 Hz	40%
4 Hz	28%
100 Hz	30%
sham	2%

Conclusion: Using alternating 15/30 Hz PENS was more effective than either 4Hz or 100 Hz frequencies in improving short-term outcomes in patients with LBP.

ii. Hsieh's randomized controlled trial compared PENS to TENS in LBP patients. (Hsieh 2002) All subjects received a core curriculum of educational materials. Patients were randomized to:

- Group 1 (n=31) received medication, including the nonsteroidal anti-inflammatory diclofenac potassium, the muscle relaxant mephenoxalone, and the antacid Wellpine.
- Group 2 (n=53) received PENS and medications. PENS involved inserting needles bilaterally into the B23 and B25 acupoints. Electrical stimulation lasted 15 minutes and used alternating 3 Hz and 15 Hz frequencies
- Group 3 (n=49) received TENS and medications. TENS electrode pads were made of brass points plated with silver. The pads were placed on the same PENS acupoints and were connected to the same electrogenerator.

A blinded examiner measured patients before, immediately after, and 1-week after treatment. The study measured outcomes with a pain VAS, a pain drawing instrument, a pressure algometer to measure pain pressure threshold, and the 100-point Quebec Back Pain Disability Scale.

Study Population: The study excluded patients due to treatment in the previous week, carcinoma, previous back surgery, bleeding disorder, ankylosing spondylitis, or inability to take oral medications.

Percent of Patients by Back Pain Duration

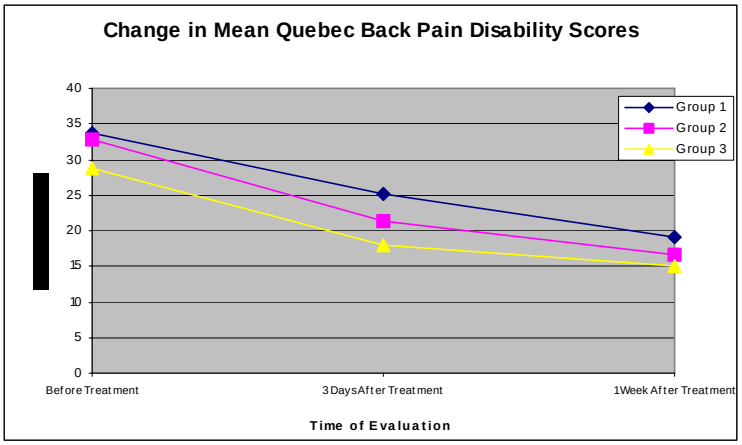
LBP Category	Definition	Percent of Patients
Acute LBP	Pain less than 1 week	56%

Subacute LBP	Pain from 1 week to 3 months	20%
Chronic LBP	Pain greater than 3 months	24%

Results: While the groups showed improvement on the pain VAS, improvement did not differ between groups 3 days or 1 week after treatment.

Change on Pain VAS by Group and Follow-up

	3-Days After Treatment	1-Week After Treatment
Medication only		1.74
PENS	1.53	1.80
TENS	1.50	2.00



Conclusion: Due to similar pain relief and functional disability improvement at 3 days and 1 week after treatment, the researchers conclude that neither PENS nor TENS had additional benefit over medication alone on LBP.

V. Insurers

Aetna's May 13, 2003 policy covers PENS units as durable medical equipment for up to a 30-day period for the treatment of chronic LBP secondary to degenerative disc disease. The policy also states that PENS is covered when used as part of a multimodality rehabilitation program that includes exercise. (Aetna 2003)

BlueCross BlueShield (BCBS) of Georgia, Iowa, and South Dakota consider PENS as medically necessary. BCBS of Georgia covers PENS for patients with appropriate conditions who have failed to obtain relief through other modalities. (BCBS GA 2002) (Wellmark 2003)

VI. Conclusions

Researchers have examined the efficacy of PNT for the treatment of LBP in case series and controlled trials. The results from case series studies suggest PNT improve LBP. However, the lack of comparison groups in these studies prohibits a conclusive statement on PNT effectiveness on improving pain and function. Hsieh's trial comparing PNT, TENS, and medication did not find statistically significant differences between treatment groups. More randomized controlled trials against sham and alternative therapies should be conducted to show the effectiveness of PNT. Until that time, PNT is considered controversial and a noncovered service.

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